REMARKS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks herewith, which place the application into condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-3, 7, 9-11, 17-29, 31-33, 37, 39-41, 43-64 and 82-93 are under examination in this application. Claims 1, 2, 17-19, 21, 24, 26, 27, 31, 32, 39, 43, 44, 46-51, 54-61 and 64 have been amended without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents. Claims 3, 7, 9-11, 20, 22, 29, 33, 34 and 37-41 have been cancelled without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents. Claims 82-93 have been added to round out the scope of protection to which Applicants are entitled.

No new matter has been added by these amendments.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. §112. The amendments of and additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support is found throughout the specification and from the pending claims.

It is further noted that this application does not claim priority to the PCT application, PCT/EP00/08781, cited by the Office Action as missing in the "Related Applications" section. The correct PCT application from which this application claims priority, PCT/FR00/02392, is listed in the "Related Applications" section and on the corrected filing receipt that was mailed on August 27, 2001.

II. THE OBJECTIONS ARE OVERCOME

The specification was objected to based on a typographical error in the table on page 39. The Abstract was further objected to because the Abstract of the Disclosure exceeded to allowable length. These issues have been corrected by this amendment.

Claims 2, 3, 7, 33 and 37 were objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 2 has been rewritten in independent form and claims 3, 7, 33 and 37 have been cancelled.

Claim 60, which was objected to due to its dependency on non-elected claims, has been rewritten to depend on claims 31 or 32.

It is respectfully submitted that the objections to the specification and claims be withdrawn since the appropriate corrections have been made.

III. THE DOUBLE PATENTING REJECTION IS OVERCOME

Claims 4-6, 8, 34-38, 42 and 65-81 of this application allegedly conflict with claims 4-6, 8, 34-38, 42 and 65-81 of U.S. application Serial No. 09/583,350. Claims 4-6, 8, 34-38, 42 and 65-81 of this application are directed to non-elected subject matter. Therefore, no conflict between the claims of the two applications exists.

Claims 1-3, 9-11, 17-29, 31-33, 37, 39-41, and 43-64 were provisionally rejected under the judicially created doctrine of obvious-type double patenting as allegedly unpatentable over claims 87, 90-97, 100, and 102-109 of copending U.S. application Serial No. 09/161,092.

The issue of whether there is indeed double patenting is contingent upon whether the claims herewith are indeed considered and entered; and, if so, whether there is indeed overlap with claims that may issue in the cited patent application. If, upon agreement as to allowable subject matter, it is believed that there is still a double patenting issue, a Terminal Disclaimer will be filed at that time. However, at this time, in view of the restriction requirements and elections in the cases, it is believed that no double patenting exists.

Accordingly, reconsideration and withdrawal of the double patenting rejection, or at least holding it in abeyance until agreement is reached as to allowable subject matter, is respectfully requested.

IV. THE REJECTIONS UNDER 35 U.S.C. § 112, 2ND PARAGRAPH, ARE OVERCOME

Claims 1-3, 7, 9-11, 17-29, 31-33, 37, 39-41 and 43-64 were rejected under 35 U.S.C. §112, second paragragh, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, it was argued that the specification fails to define "other pathologic sequelae". The amendments to claims 1 and 31 have rendered this rejection moot.

Claims 9-11 and 39-41 were also rejected under 35 U.S.C. §112, second paragragh, as being indefinite. Claims 9-11 and 39-41 have been cancelled, obviating this rejection.

Claims 24-29 and 54-59 were rejected under 35 U.S.C. §112, second paragragh, as being vague and indefinite for not stating from where the ORFs expressed in the vector are derived. This rejection is traversed. Information regarding the DNA fragments from which the ORFs are derived is clearly stated in application in the paragraph beginning on page 19, line 23.

Reconsideration and withdrawal of the §112, second paragraph, rejections are respectfully requested.

V. THE REJECTIONS UNDER 35 U.S.C. § 112, 1ST PARAGRAPH, ARE OVERCOME

The Application Provides an Adequate Written Description

Claims 1-3, 7, 9-11, 17-29, 31-33, 37, 39-41 and 43-64 were rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time of filing. The Applicants respectfully disagree. It is submitted that the present application provides an adequate written description of the claimed invention; thus, the following traverse is offered.

The lead case on the written description requirement is *In re Edwards*, 568 F.2d 1349 (C.C.P.A. 1970). The application of that case by the Federal Circuit is the state of the law on the issue. According to *Edwards*, the function of the written description requirement is to:

> [E]nsure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him; to comply with the description requirement, it is not necessary that the application describe the claimed invention in *ipsis verbis*; all that is required is that it reasonably convey to persons skilled in the art that, as of the filing date thereof, the inventor had possession of the subject matter later claimed by him.

(*Id.* at 1351-52).

Thus, determining whether the written description requirement is satisfied requires reading the disclosure in light of the knowledge possessed by a skilled artisan. Applying the law to the instant facts, it is clear possession did exist at the time of filing.

The Office Action alleges that the specification fails to define "pathologic sequelae" and how it is associated with PCV-2. Since the claims that refer to pathologic sequelae associated

with PCV-2 have been rewritten so that they no longer recite the phrase "pathologic sequelae", the rejection on this basis is moot.

The Office Action further contends that the specification allegedly fails to "define every possible immunogen capable of eliciting a humoral and/or cell-mediated immune response to PCV-2". It is further argued in the Office Action that sufficient examples demonstrating the administration of ORFs elicits an immune response. In contrast to the statements made in the Office Action regarding these points, the results of Example 10 are consistent with there being an immune response elicited in swine hosts following the administration of vectors expressing open reading frames 13 (ORF 13) and/or 4 (ORF4). In the example, it was shown that piglets to which recombinant plasmids expressing ORF13 and/or ORF4 were administered, showed a significantly reduced level of viral load in bronchial and mesenteric lymph node tissue following PCV-2 challenge. Reduction in viral load is indicative of an immune response.

It is respectfully submitted that Example 10 is sufficient to demonstrate that there in fact is an immune response generated from the administration of PCV-2 immunogen compositions, including, but not limited to, inactivated virus and vectors expressing PCV-2 immunogen DNA sequences. Furthermore, Example 10 demonstrates that the Applicant was indeed in possession of the PCV-2 immunogens claimed; thus, the written description rejection under 35 U.S.C § 112, first paragraph, is overcome.

The Application Provides an Enabling Disclosure

Claims 1-3, 7, 9-11, 17-29, 31-33, 37, 39-41 and 43-64 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable on skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant respectfully disagrees.

It is argued in the Office Action that there is insufficient data in the examples demonstrating that PCV-2 elicits the desired immune response. Applicant respectfully disagrees. In addition to the examples presented in the application, the attached Declaration of Dr. Catherine Charreyre from USSN 09/884,514 (Charreyre Declaration), demonstrates that PCV-2 elicits the desired immune response in piglets. Although vaccination was performed using inactivated PCV-2 as the immunogen, this data, taken together with the experiments presented in the specification, provide evidence that PCV-2 associated disease can be prevented and treated by administering the claimed immunogens.

According to the Court of Appeals for the Federal Circuit in the case of *In re Wands*, 8 U.S.P.Q. 2d 1400 (Fed. Cir. 1988),

> Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. 'The key word is undue, not experimentation.' The determination of what constitutes undue experimentation in a given case requires the application of standard of reasonableness, having due regard for the nature of the invention and the state of the art. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed ... [Citations omitted].

Id. at 1404.

Against this background, determining whether undue experimentation is required to practice a claimed invention turns on weighing many factors summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) For example, (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples of the invention; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims.

The assertion in the Office Action that the instant invention does not provide enablement for a method and composition for preventing myocarditis, abortion and intrauterine infection associated with a vector containing a PCV-2 ORF or immunogen is misplaced because undue experimentation would not exist. Applying *Wands* to the instant facts, it is clear that enablement exists: the quantity of experimentation necessary is low; the amount of direction or guidance presented is high; working examples are clearly present; the relative skill of those in the art is high; and the predictability of the art is also high.

It is respectfully submitted that adequate guidance is provided to enable the skilled artisan to practice the claimed invention without undue experimentation. Therefore, reconsideration and withdrawal of the U.S.C. § 112, first paragraph rejections are earnestly solicited.

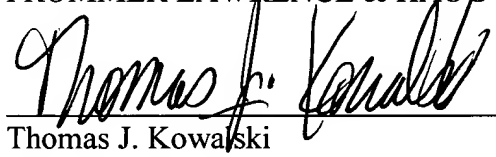
REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, prior to issuance of any paper other than a Notice of Allowance, an interview is respectfully requested; and, the Examiner is further respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for the interview.

CONCLUSION

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By: 

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

Please amend the specification, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents, as follows:

Page 39, line 3:

Values are expressed as $\log_{10}$ (number of molecules of PCV-2 in 2 µl sample).

Page 39, line 4:

Log_{10} number of PCV-2 DNA molecules

Groups	*Mean*	*std*	*N*
(A)	3.3	0.3	4
(B)[(A)]	2.9	0.7	3
Controls	3.6	0.6	4

IN THE ABSTRACT OF THE DISCLOSURE

Please amend the Abstract, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents, as follows:

Page 60, line 2:

Porcine circovirus-2 (PCV-2) is a recently identified agent [that has been associated with post-weaning multisystemic wasting syndrome (PMWS) in swine populations.] wherein [T]the potential spectrum of [disease] PCV-2-associated disease [with PCV-2 is] has been expanded by evidence of vertical and sexual transmission and associated reproductive failure in swine populations. PCV-2 was isolated from a litter of aborted piglets from a farm experiencing late term abortions and stillbirths. Severe, diffuse myocarditis was present in one piglet associated with extensive immunohistochemical staining for PCV-2 antigen. Variable amounts of PCV-2 antigen were also present in liver, lung and kidney of multiple fetuses. [The presence of other agents that have been associated with fetal lesions and abortion in swine including porcine parvovirus, porcine reproductive respiratory syndrome virus, encephalomyocarditis virus and enterovirus could not be established. Accordingly, I]Inoculation of female pigs with a composition including an immunogen from PCV-2 or an epitope of interest from such an immunogen or with a vector expressing such an immunogen or epitope of interest [(which

composition can also include an immunogen from another porcine pathogen such as porcine parvovirus or an epitope of interest therefrom or a vector expressing such an immunogen or epitope of interest, wherein the vector can co-express both the other porcine, e.g., PPV, immunogen or epitope of interest and the PCV-2 immunogen or epitope of interest, *inter alia*), e.g.,] prior to breeding, such as within the first five weeks of life, or prior to the perinatal period, or repeatedly over a lifetime, or during pregnancy, such as between the 6^{th} and 8^{th} and/or the 10^{th} and 13^{th} weeks of gestation, can prevent myocarditis, abortion and intrauterine infection associated with porcine circovirus-2[, as well as post-weaning multisystemic wasting syndrome and/or other conditions associated with PCV-2]. In addition, innoculation of male and/or female pigs with the aforementioned compositions can be carried out to prevent transmission of PCV-2 from male to female (or *vice versa*) during mating. Thus, the invention involves methods and compositions for preventing myocarditis, abortion and intrauterine infection associated with porcine circovirus-2[, as well as post-weaning multisystemic wasting syndrome and other conditions associated with PCV-2].

IN THE CLAIMS:

Please amend the claims, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents, as follows:

1. (Amended) An immunological[,] or immunogenic [or vaccine] composition for the prevention and/or treatment of porcine circovirus-2 (PCV-2)-caused myocarditis, and/or abortion and/or intrauterine infection [and/or post-weaning multisystemic wasting syndrome and/or other pathologic sequelae associated with PCV-2] comprising a pharmaceutically or veterinarily or medically acceptable carrier and an active agent comprising [a PCV-2 immunogen, or a polypeptide comprising an epitope of a PCV-2 immunogen, or an antibody elicited by a PCV-2 immunogen, or an antibody elicited by an epitope of a PCV-2 immunogen, or]a vector containing and expressing an exogenous nucleotide sequence for a PCV-2 immunogen[, or a vector expressing an epitope of a PCV-2 immunogen, or a PCV-1 immunogen that also binds to an antibody elicited by a PCV-2 immunogen or epitope, or a polypeptide comprising an epitope of a PCV-1 immunogen that also binds to an antibody elicited by a PCV-2 immunogen or epitope, or an antibody elicited by a PCV-1 immunogen that binds with both a PCV-1 immunogen or epitope and a PCV-2 epitope or immunogen, or an antibody elicited by an epitope of a PCV-1 immunogen that binds with both a PCV-1 immunogen or epitope and a PCV-

2 epitope or immunogen, or a vector expressing a PCV-1 immunogen that also binds to an antibody elicited by a PCV-2 immunogen or epitope, or a vector expressing an epitope of a PCV-1 immunogen that also binds to an antibody elicited by a PCV-2 immunogen or epitope].

2. (Amended) [The composition of claim 1]An immunological or immunogenic composition for the prevention of PCV-2-caused myocarditis and/or abortion and/or intrauterine infection comprising a pharmaceutically or veterinarily or medically acceptable carrier and an active agent comprising [a PCV-2 immunogen or a polypeptide comprising an epitope of a PCV-2 immunogen or an antibody elicited by a PCV-2 immunogen or an antibody elicited by an epitope of a PCV-2 immunogen or]a vector containing and expressing an exogenous nucleotide sequence for PCV-2 immunogen[or a vector expressing an epitope of a PCV-2 immunogen].

17. (Amended) The composition of claims 1 or 2, [7] wherein the vector comprises a DNA vector plasmid, a *E. coli*, a baculovirus, a pig herpes viruses, including Aujeszky's disease virus, a porcine adenovirus, or a poxvirus, including a vaccinia virus, an avipox virus, a canarypox virus, or[and] a swinepox virus.

18. (Amended) The composition of claim 17 wherein the vector is[comprises] a DNA vector.

19. (Amended) The composition of claim 17 wherein the vector is[comprises] a canarypox virus.

21. (Amended) The composition of claims 1 or 2,[17] additionally including at least one immunogen[or epitope] from at least one additional pig pathogen, or a vector expressing such an immunogen[or epitope], wherein the vector, the at least one immunogen from at least one additional pig pathogen, can also be the vector expressing the PCV-2 immunogen[n or epitope].

24. (Amended) The composition of claims 1 or 2,[7]wherein the vector contains and expresses an ORF selected from the group consisting of ORFs 1 to 13.

26. (Amended) The composition of claim 24, wherein the vector contains and expresses an ORF select[r]ed from the group consisting of ORFs 4, 7, 10 and 13.

27. (Amended) The composition of claim 25, wherein the vector contains and expresses an ORF select[r]ed from the group consisting of ORFs 4, 7, 10 and 13.

31. (Amended) A method for the prevention and/or treatment of porcine circovirus-2 (PCV-2)-caused myocarditis, and/or abortion and/or intrauterine infection [and/or post-weaning

multisystemic wasting syndrome and/or other pathologic sequelae]associated with PCV-2 comprising [a] inducing an immunological[,]or immunogenic [or protective]response against PCV-2 in a pig comprising administering to the pig the composition of claim 1[a composition comprising a pharmaceutically or veterinarily or medically acceptable carrier and an active agent comprising a PCV-2 immunogen, or a polypeptide comprising an epitope of a PCV-2 immunogen, or an antibody elicited by a PCV-2 immunogen, or an antibody elicited by an epitope of a PCV-2 immunogen, or a vector expressing a PCV-2 immunogen, or a vector expressing an epitope of a PCV-2 immunogen, or a PCV-1 immunogen that also binds to an antibody elicited by a PCV-2 immunogen or epitope, or a polypeptide comprising an epitope of a PCV-1 immunogen that also binds to an antibody elicited by a PCV-2 immunogen or epitope, or an antibody elicited by a PCV-1 immunogen that binds with both a PCV-1 immunogen or epitope and a PCV-2 epitope or immunogen, or an antibody elicited by an epitope of a PCV-1 immunogen that binds with both a PCV-1 immunogen or epitope and a PCV-2 epitope or immunogen, or a vector expressing a PCV-1 immunogen that also binds to an antibody elicited by a PCV-2 immunogen or epitope, or a vector expressing an epitope of a PCV-1 immunogen that also binds to an antibody elicited by a PCV-2 immunogen or epitope].

32. (Amended) [The method of claim 31]A method for the prevention of PCV-2-caused myocarditis and/or abortion and/or intrauterine infection comprising inducing an immunological or immunogenic response against PCV-2 in a pig comprising administering to the pig the composition of claim 2[a composition comprising a pharmaceutically or veterinarily or medically acceptable carrier and an active agent comprising a PCV-2 immunogen or a polypeptide comprising an epitope of a PCV-2 immunogen or an antibody elicited by a PCV-2 immunogen or an antibody elicited by an epitope of a PCV-2 immunogen or a vector expressing a PCV-2 immunogen or a vector expressing an epitope of a PCV-2 immunogen].

43. (Amended) The method of claims 31 or 32,[33] wherein the composition additionally includes at least one immunogen[or epitope] from at least one additional pig pathogen or a vector expressing such an immunogen[or epitope].

44. (Amended) The method of claim 43 wherein the composition additionally includes at least one immunogen[or epitope]from at least one additional pig pathogen.

46. (Amended) The method of claim 45,[43] wherein the at least one additional pig pathogen is[comprises] porcine parvovirus (PPV).

47. (Amended) The method of claims 31 or 32,[37] wherein the vector comprises a DNA vector plasmid, a *E. coli*, a baculovirus, a pig herpes viruses, including Aujeszky's disease virus, a porcine adenovirus, or a poxvirus, including a vaccinia virus, an avipox virus, a canarypox virus, or[and] a swinepox virus.

48. (Amended) The method of claim 47, wherein the vector is[comprises] a DNA vector.

49. (Amended) The method of claim 47, wherein the vector is[comprises] a canarypox virus.

50. (Amended) The method of claim 31,[37] additionally including at least one immunogen[or epitope] from at least one additional pig pathogen, or a vector expressing such an immunogen[or epitope], wherein the vector, the at least one immunogen from at least one additional pig pathogen, can also be the vector expressing the PCV-2 immunogen[or epitope].

51. (Amended) The method of claim 32,[47] additionally including at least one immunogen[or epitope] from at least one additional pig pathogen, or a vector expressing such an immunogen[or epitope], wherein the vector, the at least one immunogen from at least one additional pig pathogen, can also be the vector expressing the PCV-2 immunogen[or epitope].

54. (Amended) The method of claims 31 or 32,[37] wherein the vector contains and expresses an ORF selected from the group consisting of ORFs 1 to 13.

55. (Amended) The method[composition] of claim 47, wherein the vector contains and expresses an ORF selected from the group consisting of ORFs 1 to 13.

56. (Amended) The method of claim 54, wherein the vector contains and expresses an ORF select[r]ed from the group consisting of ORFs 4, 7, 10 and 13.

57. (Amended) The method of claim 55, wherein the vector contains and expresses an ORF select[r]ed from the group consisting of ORFs 4, 7, 10 and 13.

58. (Amended) The method of claim 54, wherein the vector contains and expresses ORF 4 and/or 13.

59. (Amended) The method of claim 55, wherein the vector contains and expresses ORF 4 and/or 13.

60. (Amended) The method of claims 31 or 32,[33] wherein the immunogen[or epitope] is recombinantly produced.

62. (Amended) The method of claims 31 or 32, wherein the pig is a female pig.

64. (Amended) The method of claims 31 or 32, wherein the pig is a male pig.

ABSTRACT OF THE DISCLOSURE

Porcine circovirus-2 (PCV-2) is a recently identified agent wherein the potential spectrum of PCV-2-associated disease has been expanded by evidence of vertical and sexual transmission and associated reproductive failure in swine populations. PCV-2 was isolated from a litter of aborted piglets from a farm experiencing late term abortions and stillbirths. Severe, diffuse myocarditis was present in one piglet associated with extensive immunohistochemical staining for PCV-2 antigen. Variable amounts of PCV-2 antigen were also present in liver, lung and kidney of multiple fetuses. Inoculation of female pigs with a composition including an immunogen from PCV-2 or an epitope of interest from such an immunogen or with a vector expressing such an immunogen or epitope of interest prior to breeding, such as within the first five weeks of life, or prior to the perinatal period, or repeatedly over a lifetime, or during pregnancy, such as between the 6th and 8th and/or the 10th and 13th weeks of gestation, can lower viral titer prevent myocarditis, abortion and intrauterine infection associated with porcine circovirus-2. In addition, innoculation of male and/or female pigs with the aforementioned compositions can be carried out to prevent transmission of PCV-2 from male to female (or *vice versa*) during mating. Thus, the invention involves methods and compositions for preventing myocarditis, abortion and intrauterine infection associated with porcine circovirus-2.